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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/635,091

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Anne M. Pianca

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EXAMINER

KAHELIN, MICHAEL WILLIAM

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/635,091	<b>Applicant(s)</b> PIANCA ET AL.	
	<b>Examiner</b> MICHAEL KAHRELIN	<b>Art Unit</b> 3762	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 October 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 14-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION**

***Election/Restrictions***

1. Applicant's election with traverse of Group I (claims 1-13) in the reply filed on 10/7/2008 is acknowledged. The traversal is on the ground(s) that (1) the characterization of Group II is not commensurate with the scope of claims 14-21 because claim 14 does not require a blunt tip; (2) that groups I and II are not mutually exclusive because a stylet can have both an "outer covering set over an inner core" and "variable material properties and a blunt tip"; (3) claims 2 and 11 of Group I recite the distinct elements of Group II; and (4) that restriction after such substantial prosecution is not the best use of PTO and Applicant resources. This is not found persuasive because (1) the characterization of Groups I and II are not the basis of restriction. The basis of restriction (description of how the groups are distinct) is set forth in paragraph 2 of the previous Office Action. In regards to the argument that the groups do overlap in scope and not mutually exclusive, mutual exclusivity is not a prerequisite for restriction practice, and the fact that the two groups share limitations/elements does not mean that they have overlapping scope. Scope is overlapping if all limitations of one of the groups is included in the other group (e.g., groups with claim elements AB and ABC are overlapping, but groups with claim elements AB and AC are not overlapping). In regards to the argument that claims 2 and 11 also recite "variable material properties," the specific claim limitations of group II are not included in claims 2 and 11. In regards to the argument that restriction after such substantial prosecution is not the best use of PTO and Applicant resources, the current claims have not yet been examined. Various

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other claim sets have been examined, but not the current claim set that was amended to recite distinct inventions.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 14-21 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 10/7/2008.

***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Regarding claim 1, although the examiner was able to find support for the limitation of an outer covering "set over" the inner core, he was unable to find support in the originally-filed disclosure that the outer covering and inner core are "fix[ed]." Further, the examiner was unable to find support for an outer covering that extends from a proximal end of the stylet to a distal tip of the stylet. Figure 2 fails to show the composition of the stylet over this length (but merely at the

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location of figure 3), and figures 4 and 5 fail to show the proximal end and distal tip of the stylet.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1, 5-11, and 13 are rejected under 35 U.S.C. 102(e) as being anticipated by Soukup (US 6,755,794, hereinafter "Soukup").

7. In regards to claim 1, Soukup discloses a metal outer covering material extending from a proximal end of a stylet to a distal tip (Fig. 1, element 14); a solid inner core made of inner core material and having a solid lateral cross-section (element 12; col. 5, lines 15-21); wherein the outer and inner materials have different elastic and buckling properties (col. 5, lines 14-16 and 23-24); and where in the outer covering is set over the inner core to fix the outer covering over the inner core (Fig. 1; col. 3, lines 31-33).

8. In regards to claim 5, the stylet is isodiametric (Figs. 2 and 3).

9. In regards to claims 6 and 8, the outer covering has a variable wall thickness/circumference in the "loosened state" Figure 1.

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**10.** In regards to claims 7 and 9, the outer covering has a substantially constant wall thickness in the “tightened state” of Figures 2 and 3, and the wall itself (ribbon 14) has a “substantially constant wall thickness in either state (Figs. 1-3).

**11.** In regards to claim 10, the core has a substantially constant thickness along the length of the stylet (Fig. 1).

**12.** In regards to claim 11, the core is Nitinol and the covering material is stainless steel (col. 5, lines 14-16 and 23-24).

**13.** In regards to claim 13, the inner core has been “pre-stressed” to operate on the compression side of the stress-strain curve (col. 2, lines 52-61).

***Claim Rejections - 35 USC § 103***

**14.** The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**15.** This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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**16.** Claims 2-4 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Soukup. Soukup discloses the essential features of the claimed invention except for the claimed stainless steel alloys, or that the outer covering is a super-elastic material and the inner core is a linear elastic material. It is well known to provide stylets with the claimed stainless steel alloys to provide the predictable results of using a readily available and biocompatible material, and to provide outer coverings of a super-elastic material and inner cores of linear elastic material to provide the predictable result of a stylet with the desired combination of mechanical properties. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Soukup's invention by providing the claimed stainless steel alloys to provide the predictable results of using a readily available and biocompatible material, and to provide an outer covering of a super-elastic material and inner core of linear elastic material to provide the predictable result of a stylet with the desired combination of mechanical properties.

### ***Response to Arguments***

**17.** Applicant's arguments filed 4/16/2008 have been fully considered but they are not persuasive. Applicant argued that the amended limitation of "set over the inner core to fix the outer covering over the inner core" has support in the originally-filed disclosure because of a dictionary definition including "to fix" that is consistent with the usage of the word "set" in the disclosure. However, the support for this amendment must be in the disclosure.

**18.** In regards to the art rejections, Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection, necessitated by amendment.

***Conclusion***

**19.** The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Gates (US 5,522,875) is one of many teachings of the claimed stainless steel alloys and a super-elastic sheath over a linear elastic core.

**20.** Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **MICHAEL KAHELIN** whose telephone number is (571)272-8688. The examiner can normally be reached on M-F, 8-4.



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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

\*\*\*

/Michael Kahelin/  
Examiner, Art Unit 3762

/Angela D Sykes/  
Supervisory Patent Examiner, Art Unit 3762